

REMARKS

Status of Claims

Claims 23-38 are currently pending and under consideration.

Claim Amendments

Claim 23 has been added to incorporate the subject matter of claim 32 as well as the subject matter contained on page 4, lines 28-32 of the specification. – the fenofibric acid content comprises 5 to 60% of the total weight of the composition. This percentage is based on only the deprotonated fenofibric acid, since the salts and their molecular weight can vary. In view thereof, claim 32 has been deleted. No new matter has been added as a result of these claim amendments.

Interview Summary and Rejection of Claims 23-38 Under 35 USC Section 103(a)

The undersigned attorney would like to thank the Examiner for the courtesy of the telephonic interview conducted between the Examiner, the undersigned attorney and attorney Jon Kim on February 22, 2010. During the interview, the rejection of claims 23-38 under 35 U.S.C. Section 103(a) as being unpatentable over Boyer (U.S. Patent No. 4,8000,079) in view of Kothrade et al. (U.S. Patent No. 6,284,803) was discussed. As discussed during the interview, Boyer teaches compositions containing fenofibrate and does not disclose or suggest compositions containing fenofibric acid or salts of fenofibric acid. Kothrade et al. is directed to solid dosage forms that comprise a polymeric binder and an active ingredient, wherein the polymeric binder consists of copolymerized units of (1) 15-83% w/w of at least one N-vinylactam; (2) 15-83% w/w of methyl methacrylate; (3) 2-70% of at least one other monomer; and (4) 9-9.9% w/w of at least one α,β -ethylenically unsaturated acid. Kothrade et al. teach in detail how to make the polymeric binder. However, Kothrade et al. do not disclose or suggest fenofibric acid. Thus, neither Boyer nor Kothrade et al., either individually or collectively, disclose or suggest formulating fenofibric acid into a composition.

Specifically, during the telephonic interview, Ms. Mueller and Mr. Kim discussed with the Examiner how even though fenofibric acid is technically encompassed within Formula I of Boyer, that a reading of Boyer **in its entirety** would make it abundantly clear to one skilled in the art that Boyer's invention relates to **fenofibrate** and formulations (namely, microgranules) to improve the absorption of fenofibrate in the digestive system and not to fenofibric acid. Specifically, in column 2, lines 3-8, Boyer states, “[I]t has been observed that fenofibrate has poor solubility in aqueous liquids, thereby giving rise to non-uniform absorption in the digestive tube, and in accordance with the present invention a galenical preparation has been devised which considerably improves absorption by the digestive tube (emphasis added).” In

short, Boyer teaches microgranules of fenofibrate to improve its solubility and absorption. As discussed several times during the interview, fenofibrate is **highly water insoluble**. In contrast, fenofibric acid is **highly water soluble**. This is a key difference between the two compounds. One skilled in the art would have no need for the teachings of Boyer for fenofibric acid and its salts, since fenofibric acid is highly water soluble. Therefore, there is no need to micronize fenofibric acid using Boyer's microgranulation method.

During the interview, the Examiner suggested that Applicants amend claim 23 to include the limitations of claim 32. Applicants have herein made this amendment to claim 23 in order to expedite prosecution. Applicants submit that this amendment to claims overcomes the rejection of claims 23-38 under 35 U.S.C. Section 103(a) as being unpatentable over Boyer (U.S. Patent No. 4,8000,079) in view of Kothrade et al. (U.S. Patent No. 6,284,803).

In view thereof, Applicants submit that that this rejection is now moot and should be withdrawn.

REQUEST FOR RECONSIDERATION

Reconsideration and withdrawal of all claim rejections are respectfully requested. Applicants believe that the present application is in condition for allowance. Should the Office have any questions or would like to discuss any matters in connection with the present application, the Office is invited to contact the undersigned at

Polsinelli Shughart

160 N. Clark Street
Suite 4200
Chicago, IL 60601
(312)-873-3632 (Phone)
(312)-873-2932 (Fax)
lmueller@polsinelli.com

Date:

Direct telephone calls to:

Respectfully submitted,

/Lisa V. Mueller/

Lisa V. Mueller
Attorney for Applicant
Reg. No. 38,978

March 31, 2010

312.873.3632